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| EXAMINER |
|---|
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| ART UNIT | PAPER NUMBER |
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| 1645 | 14 |

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/662,812 | Applicant(s) Murden et al |
|---|---|---|
| | Examiner Portner | Art Unit 1645 |

*-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Apr 21, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *3-6, 8-11, and 35-41* is/are pending in the application.

4a) Of the above, claim(s) *3-6,9,35-37,38,40-41, 8 (b-c), 10-11(b-c),39(b-c)* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8a,10a,11a,39a* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *3-6, 8-11, and 35-41* are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

**DETAILED ACTION**

Claims 1,2,7,12-14,15-18, 19, 20-34 have been canceled.

Claims 3-6, 8-11,35-37 and new claims 38-41 are pending.

Claims 8-11 have been amended. New claims 38-41 have been added.

Claims 3-6, 9, 35-37, 38, 40-41 and non-elected subparagraphs of claims 8, 10-11, 39 stand withdrawn from consideration.

Claims 8a, 10a, 11a , and 39(a) are under consideration.

***Sequence Letter***

1. This application is now in sequence compliance.

***Election/Restriction***

2. Newly submitted claim 38, 40-41 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims 38, 40-41 are is directed to a non-elected embodiment not examined in the First Action dated October 23, 2002.

a.The optional second nucleic acid of original claim 8 was a non-elected invention; the elected invention was a nucleic acid encoding the amino acid sequence of SEQ ID NO 2 or a nucleic acid molecule of SEQ ID NO 1.

b. No immunogenic fragment of SEQ ID No 2 were examined in the First Office Action. This embodiment was/is a non-elected invention.

c. No modified nucleic acid molecules that encode an immunogenic polypeptide that share from 75% identity with the amino acid sequence of SEQ ID NO 2 were examined in the First Office Action. This embodiment was/is a non-elected invention.

An isolated nucleic acid molecule with 100% sequence identity was applied against the claims. NO additional inventions were examined in the First Action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 38, 40-41 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Rejections Withdrawn***

3. Claims 1-2 and 7 directed to nucleic acid molecules that have not been isolated and purified and therefore reads on a product of nature; the claimed invention is directed to non-statutory subject matter, in light of the cancellation of the claims.

4. Rejections over claims canceled are withdrawn.

***Claim Objections and Rejections Maintained***

5. Claims 8(a), 10(a), 11(a) and new claim 39(a) are objected to because of the following informalities: All of the claims recite non-elected inventions. Appropriate correction is required.

6. Claims 8(a), 10(a), 11(a) and new claim 39(a) are rejected under 35 U.S.C. 112, first paragraph, as previously applied to claims 8(a), 10(a)-11(a) because the specification, while being enabling for a nucleic acid molecule that comprises a nucleic acid sequence of SEQ ID NO 1 and encodes SEQ ID No 2, does not reasonably provide enablement for the utilization of the nucleic acid molecule as a vaccine or pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. Claims 8(a), 10(a; the phrase "control sequence" is being read to include sequences defined at page 23, lines 9-33, to include a start codon (ATG) which would provide means for expression of the encoded polypeptide in a mammalian cell), 11(a), 39(a) (in so far as the claims

are directed to SEQ ID NO 1, a nucleic acid that encodes SEQ ID No 2, a vector and host cell that comprises SEQ ID NO 1 or encodes SEQ ID No 2) are rejected under 35 U.S.C. 102(a) as being anticipate by Kalman et al (April 1999) for reasons of record in paper # 11, paragraph 13.

***Response to Arguments***

8. Applicant's arguments filed April 21, 2003 have been fully considered but they are not persuasive.

9. The rejection of claims 8(a), 10(a), 11(a) and new claim 39(a) under 35 U.S.C. 112, first paragraph (scope), as previously applied to claims 8(a), 10(a)-11(a) because the specification, while being enabling for a nucleic acid molecule that comprises a nucleic acid sequence of SEQ ID NO 1 and encodes SEQ ID No 2, does not reasonably provide enablement for the utilization of the nucleic acid molecule as a vaccine or pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, is traversed on the grounds that:

a. "The polypeptide of SEQ ID NO 2 is expressed, i.e.,pCAmgp002 (Figure 3)" provided immune protection of mice against intranasal challenge.

10. It is the position of the examiner that the embodiment used to traverse the scope of enablement rejection is not claimed. Figure 4 also shows an outer membrane protein of Chlamydia that did not induce a protective immune response (pCABk917). Induction of a protective immune response is unpredictable in the art and this fact is supported by the data provided in Figure 4. The combination of a pCMV promoter/plasmid/nucleic acid molecule of

SEQ ID NO 1, encodes SEQ ID NO 2 is a combination composition that is not specifically claimed. The combination is critical for induction of the immune response used to traverse the instantly claimed invention.

Claim 8 recites the phrase "one or more control sequences for expression of the polypeptide in a mammalian cell"; this phrase is defined to include various sequences at page 23, lines 9-33 of the instant specification and includes the sequence ATG. The instantly claimed invention does not comprise the critical pCMV virus promoter; specifically plasmid pCAmgp002.

It was also noted that Figure 3 shows pCA mg 002 and Figure 4 shows pCA mgp 002. These two plasmids are defined by two different reference designators. How they differ has not been pointed out. The critical characteristics required for induction of a protective immune response are not claimed.

Additionally claim 8 does not require the nucleic acid to be in association with a pCMV virus promoter through the recitation of "is integrated and expressed in a bacterial cell". No compositions that comprise any bacterial cell that comprises SEQ ID NO 2 have been shown to induce a protective immune response.

Chlamydia pneumoniae strain CWL029 which comprises SEQ ID NO 1 and encodes SEQ ID NO 2, has this nucleic acid integrated into the bacterial cell and expresses the encoded outer membrane protein; CWL029 is a pathogenic strain of bacteria that causes infection and would not serve as bacterial cell vaccine vector. Any and all bacteria would not serve as vaccine vectors. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

The scope of enablement rejection is maintained for reasons of record in paper number 11, and arguments set forth above.

Amendment of the claims to recite the claim limitations argued to be critical could possibly obviate this rejection.

11. The rejection of claims 8(a), 10(a), 11(a), and new claim 39(a) (in so far as the claims are directed to SEQ ID NO 1, a nucleic acid that encodes SEQ ID No 2, a vector and host cell that comprises SEQ ID NO 1 or encodes SEQ ID No 2) are rejected under 35 U.S.C. 102(a) as being anticipate by Kalman et al (April 1999) is traversed on the grounds that:

a. The compositions of Kalman et al are asserted to not to be "vaccines and pharmaceutical compositions";

b. Kalman does not provide any expression data.

c. Kalman does not disclose or suggest expression the sequences;

d. Kalman et al is asserted to lack the structural feature of being operatively linked to one or more control sequences for expression of the polypeptide as specified by Applicant's claims.

12. It is the position of the examiner that:

a. Kalman et al was applied to the claims based upon the components contained in the composition. The recitation of the terms vaccine and pharmaceutical composition can be read both as a recited intended use and/or a functional characteristic of the composition.

b. Kalman discloses Chlamydophia pneumoniae CWL029 which comprises SEQ ID NO 1 integrated into the bacterial chromosome, and expressed the encoded outer membrane protein SEQ ID NO 2; Amended claim 8 reads on Chlamydophia pneumoniae CWL029, in light of the fact that the nucleic acid need not be heterologous to the bacterial cell into which it is integrated. Additionally, the control sequence for expression includes ATG, as defined in the instant specification at page 23, which does not require the nucleic acid to be expressed as this portion of the claim is set forth in the future tense.

With respect to "integrated and expressed in a bacterial cell", Kalman et al integrated the nucleic acid into M13 vector. The nucleic acid was maintained in a viable clone from which PCR primer could amplify the coding sequence for determination of the encoded protein's functionality to be polymorphic outer membrane proteins, Family G (see page 388, col. 1, last paragraph; nucleic acid annotation for nucleic acids ranging from 11384 to 13290 and given a gene number of Cpn0021). Expression of the encoded polypeptide/protein by CWL029 allowed the functionality of the protein to be determined (see page 388, col. 1, last paragraph and first paragraph in col. 2).

c. Proteins are encoded by expressed genes. Therefore Kalman et al provide expression data by disclosing data on a new family of chlamydial polymorphic membrane proteins, encoded and expressed in bacterial strain CWL029.

d. Expression of the encoded protein resulted from being operatively linked to a control sequence such as "ATG", which permits expression of the nucleic acid.

The reference still anticipates the instantly claimed invention as now claimed for reasons of record and arguments set forth above.

Amendment of the claims to recite a heterologous pCMV virus eukaryotic promoter operatively linked to SEQ ID NO 1 could obviate this rejection.

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
June 24, 2003

LYNETTE R. F. SMITH
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